INION
Intelligent Solution

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510(k) SUMMARY

Inion Hexalon™ Biodegradable ACL/PCL Screw

AUG - 3 2007

Manufacturer and submitter
Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND

Contact Person
Kati Marttinen, Regulatory Affairs Specialist
Phone: +358 10 830 6600
Fax: +358 10 830 6691
kati.marttinen@inion.com

Establishment registration number
9710629

Trade name of the device
Inion Hexalon™ Biodegradable ACL/PCL Screw

Device classification and product code
Class II
Classification Panel: Orthopedic
Product Code: HWC
Common name: Biodegradable Interference Screw
Regulation number: 21 CFR 888.3040

Predicate devices
Arthrex Interference Screw (K062466)
Arthrex Tenodesis Screw Family (K041356)
Biomet Bio-Core Interference Screw (K042552)
Biomet Resorbable Interference Screw (K041274)

Conformance with performance standards
No applicable mandatory performance standards exist for this device.
Compliance to voluntary consensus standards is listed in the application.

Device description and principles of operation

Inion Hexalon™ Biodegradable ACL/PCL Screw is made of resorbable polylactic acid / trimethylenecarbonate copolymer. The Inion Hexalon™ Biodegradable Screws are coloured green for better visualization during surgical operation.

Inion Hexalon™ Biodegradable ACL/PCL Screws gradually lose their strength during 18-36 weeks. Bioresorption takes place within two to four years. Inion Hexalon™ Biodegradable ACL/PCL Screw is sterile and non-collagenous. The shelf life of the product is three years.

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Indications for use

The Inion Hexalon™ Biodegradable ACL/PCL Screw is intended for soft tissue (including ligament, tendon, and bone-tendon-bone graft) fixation to bone in surgeries of the knee, shoulder, elbow, ankle, foot, hand and wrist where the offered screw sizes are patient appropriate.

Substantial equivalence to marketed products

The evidence demonstrates that the intended use, material composition and scientific technology, degradation profile and mechanical properties of Inion Hexalon™ Biodegradable ACL/PCL Screw are substantially equivalent with the predicate devices.

Inion Hexalon™ Biodegradable ACL/PCL Screw is substantially equivalent to predicate Class II devices, when used for soft tissue (including ligament, tendon, and bone-tendon-bone graft) fixation to bone in surgeries of the knee, shoulder, elbow, ankle, foot, hand and wrist where the offered screw sizes are patient appropriate, because the differences between Inion Hexalon™ Biodegradable ACL/PCL Screw and the predicate devices do not raise new questions of safety and effectiveness.

Inion Oy
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2007

Inion Oy
% Ms. Kati Marttinen
Regulatory Affairs Specialist
Lääkärinkatu 2,
FIN-33520 Tampere, FINLAND

Re: K071464
Trade/Device Name: Inion Hexalon™ Biodegradable ACL/PCL Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, JDR, MAI
Dated: May 25, 2007
Received: May 29, 2007

Dear Ms. Marttinen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071464

Device Name: Inion Hexalon™ Biodegradable ACL/PCL Screw

Indications for use:

The Inion Hexalon™ Biodegradable ACL/PCL Screw is intended for soft tissue (including ligament, tendon, and bone-tendon-bone graft) fixation to bone in surgeries of the knee, shoulder, elbow, ankle, foot, hand and wrist where the offered screw sizes are patient appropriate.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071464